3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO-P-2021-0061]

RIN 0651-AD59

Establishing Permanent Electronic Filing for Patent Term Extension Applications

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) proposes to amend the Rules of Practice in Patent Cases to require that patent term extension (PTE) applications, interim PTE applications, and any related submissions to the USPTO be submitted electronically via the USPTO patent electronic filing system (EFS-Web or Patent Center). The proposed rule changes would reduce the administrative burden on PTE applicants. They also would further advance the USPTO's information technology (IT) strategy to achieve complete beginning-to-end electronic processing of patent-related submissions, thereby improving administrative efficiency by facilitating electronic file management, optimizing workflow processes, and reducing processing errors.

DATES: Comments must be received by **[INSERT DATE 60 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]** to ensure consideration.

ADDRESSES: For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, enter docket number PTO-P-2021-0061 on the homepage and click "Search." The site will provide a search results page listing all documents associated with this docket. Find a reference to this document and click on the "Comment Now!" icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in Adobe® portable document format (PDF) or Microsoft Word® format. Because comments will be made available for public inspection, information that the submitter does

not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of, or access to, comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-0909; or Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-7728. You can also send inquiries to patentpractice@uspto.gov.

SUPPLEMENTARY INFORMATION: PTE under 35 U.S.C. 156 enables the owners of patents that claim certain human drug products, medical device products, animal drug products, veterinary biological products, and food or color additive products to restore to the terms of those patents some of the time lost while awaiting premarket Government approval for the products from a regulatory agency. *See, e.g.*, section 2750 of the Manual of Patent Examining Procedure (MPEP, Ninth Edition, R-10.2019). The USPTO administers 35 U.S.C. 156 in partnership with the relevant regulatory agencies (i.e., the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA)). As part of its administration, the USPTO sends to the relevant agency a copy of any initial submission for PTE that the USPTO receives (i.e., a copy of any PTE application under 35 U.S.C. 156(d)(1) and 37 CFR 1.740 or any interim PTE application under 35 U.S.C. 156(d)(5) and 37 CFR 1.790).

Prior to the COVID-19 pandemic, the USPTO prohibited the electronic filing of initial submissions for PTE. *See* section B2 of the Legal Framework for Patent Electronic System, available at www.uspto.gov/patents/apply/filing-online/legal-framework-efs-web, and section 502.05(I)(B)(2) of the MPEP. Requiring initial PTE submissions, which often comprise hundreds of pages, to be physically filed in triplicate under 37 CFR 1.740(b) was viewed as the most effective way to minimize processing errors.

Due to the workplace changes caused by the COVID-19 pandemic, the USPTO waived its prohibition on the electronic filing of initial submissions for PTE and the triplicate copy requirements in 37 CFR 1.740(b) and 1.790(b). *See* Relief Available to Patentees in View of the COVID-19 Outbreak for Submission of Initial Patent Term Extension Applications Filed Pursuant to 35 U.S.C. 156, 1475 Off. Gaz. Pat. Office 234 (June 23, 2020). The waiver did not impact related follow-on submissions to the USPTO, which were already permitted to be filed electronically prior to the pandemic.

Through informal feedback received during the processing of PTE applications, stakeholders have thus far communicated unanimous support for electronic filing of initial PTE submissions. Additionally, the USPTO and its partner agencies have successfully implemented a system by which the USPTO electronically transmits a copy of any initial submission for PTE to the relevant agency. The new system has not caused any processing errors.

Accordingly, the USPTO is proposing to change its rules of practice to require that PTE applications, interim PTE applications, and any related submissions to the USPTO be submitted electronically via the USPTO patent electronic filing system. The proposed rule changes are designed to streamline the filing of PTE applications and related documents and minimize paper handling. As has been the case since the June 2020 implementation of the electronic filing waiver, the proposed rule changes will result in PTE applications being viewable in USPTO patent electronic viewing systems (the Patent Application Information Retrieval (PAIR) system or Patent Center) immediately upon filing. Additionally, the changes would permit the USPTO to more efficiently allocate the personnel and physical space it currently deploys for the handling of physical copies of PTE submissions.

If the proposed rule changes are adopted, PTE applicants must use the correct document description to ensure that USPTO personnel are timely apprised of electronic submissions. "Patent Term Extension Application Under 35 USC 156" (Doc Code TERM.REQ) is the correct document description for a PTE application under 35 U.S.C. 156(d)(1) and 37 CFR

1.740, and "Interim Patent Term Extension Application Under 35 USC 156(d)(5)" (Doc Code TERM.REQ.ITM) is the correct document description for an interim PTE application under 35 U.S.C. 156(d)(5) and 37 CFR 1.790. The USPTO has also created the new document descriptions "Interim Patent Term Extension Request Under 35 USC 156(e)(2)" (Doc Code TERM.REQ.E2) for requests for interim extension of the patent term under 35 U.S.C. 156(e)(2) and 37 CFR 1.760, and "Disclosure Under 37 CFR 1.765 in a Patent Term Extension Application" (Doc Code TERM.DISCL) for disclosures to the USPTO under 37 CFR 1.765. PTE applicants are reminded that, when multiple PTE applications are filed for different patents based on the same regulatory review period, it is incumbent upon the PTE applicants to inform the USPTO of the various PTE applications, pursuant to 37 CFR 1.740(a)(13) and 37 CFR 1.765. *See also* section 2761 of the MPEP.

In addition, the USPTO has created the new document description "Limited POA and/or Change of Address for a Patent Term Extension Application" (Doc Code PTE.POA) for limited powers of attorney and/or changes of correspondence address that are filed specifically for PTE applications. Although a power of attorney or limited power of attorney is not required for a practitioner to prosecute a PTE application (practitioners may prosecute PTE applications by acting in a representative capacity pursuant to 37 CFR 1.34), the USPTO routinely receives limited powers of attorney specifying that the power is limited to prosecution of the PTE application. A limited power of attorney filed using the document description "Limited POA and/or Change of Address for a Patent Term Extension Application" (Doc Code PTE.POA) will not be processed by the Office of Patent Application Processing (OPAP) and will not serve to change an existing power for the underlying patent or establish power for the underlying patent.

As for a change of the correspondence address that is filed specifically for a PTE application, the USPTO uses the 37 CFR 1.740(a)(15) address provided in an initial PTE or interim PTE application strictly for communications regarding the PTE application. If a PTE applicant subsequently wishes to change the 37 CFR 1.740(a)(15) address, the document description

“Limited POA and/or Change of Address for a Patent Term Extension Application” (Doc Code PTE.POA) should be used for the submission. A change of address filed using the document description “Limited POA and/or Change of Address for a Patent Term Extension Application” (Doc Code PTE.POA) will not be processed by the OPAP and will not serve to change the correspondence address for the underlying patent. PTE applicants are reminded to separately file a change of address with any other relevant regulatory agency to timely receive copies of correspondence from that agency.

PTE applicants are strongly encouraged to confirm that they have used the correct document description for any PTE submission, especially time-sensitive PTE submissions, such as interim PTE applications under 35 U.S.C. 156(d)(5) and 37 CFR 1.790. Use of the correct document description may be verified by reviewing the EFS Acknowledgement Receipt (Doc Code N417) issued for the submission. In addition, both the document description and code for a submission may be verified in the electronic application file. If a mistake is identified, PTE applicants should contact the Patent Electronic Business Center at 866-217-9197 or EBC@uspto.gov.

When electronically filing a PTE or interim PTE application, the PTE or interim PTE application, including all exhibits, attachments, or appendices, should be submitted as a single file. If the single file comprising the application and its exhibits, attachments, or appendices exceeds the upload limit of the USPTO patent electronic filing system, the file may be split into smaller files to permit uploading, but the number of separate files to be uploaded should be minimized. Additionally, when splitting a file into smaller files, the order of the exhibits, attachments, or appendices as mentioned in the application should be maintained, and a single exhibit, attachment, or appendix should not be split, if possible. The USPTO has created a new document description, “Continuation of Patent Term Extension Application” (Doc Code PTE.APPENDIX), to be used for any exhibit, attachment, or appendix to a PTE or interim PTE application that is filed separately from the application.

Discussion of Specific Rules

The following is a discussion of the proposed amendments to 37 CFR part 1.

Section 1.740: Section 1.740(a)(15) is proposed to be amended to require the provision of an email address of the person to whom inquiries and correspondence related to the PTE application are to be directed. The USPTO has found that the availability of an email address facilitates contact with the PTE applicant's representative.

Section 1.740(b) is proposed to be amended to require that PTE applications under § 1.740, and any related submissions to the USPTO, be submitted using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements. Submissions to the USPTO related to PTE applications under § 1.740 include any related follow-on documents that must be submitted to the USPTO, such as corrections of informalities under § 1.740(c), petitions requesting review of incomplete filings or review of an accorded filing date under § 1.741(b), requests for reconsideration of notices of final determination and responses to requirements for information under § 1.750, requests for 35 U.S.C. 156(e)(2) interim extensions under § 1.760, disclosures to the USPTO under § 1.765, express withdrawals under § 1.770, and replies to requests to identify the holder of an approval under § 1.785(d). PTE-related submissions to the FDA or the USDA, such as disclosures to the Secretary of Health and Human Services or the Secretary of Agriculture under § 1.765, should continue to be filed directly with the relevant agency. The proposed amendment of § 1.740(b) would remove the requirement in the current § 1.740(b) to file each PTE application in triplicate.

Section 1.741: Section 1.741(a) is proposed to be amended to provide that the filing date of a PTE application is the date on which a complete PTE application is either received in the USPTO via the USPTO patent electronic filing system or filed pursuant to the procedure set forth in § 1.8(a)(1)(i)(C) and (a)(1)(ii). The provision in the current § 1.741(a), which provides that the filing date of a PTE application may be the date on which a complete application is filed pursuant to the physical mailing or facsimile transmission procedures set

forth in §§ 1.8(a)(1)(i)(A) or (B) or 1.10, is proposed to be removed in view of the proposed requirement to file PTE applications via the USPTO patent electronic filing system.

Section 1.770: Section 1.770 is proposed to be amended to remove the requirement to file duplicates of express declarations of withdrawal of PTE applications. The requirement would no longer be needed in view of the proposed requirement to file submissions related to PTE applications via the USPTO patent electronic filing system.

Section 1.790: Section 1.790(a) is proposed to be amended to clarify that the referenced paragraphs are paragraphs of 35 U.S.C. 156(g). Additionally, the time periods in the current § 1.790(a) for filing initial and subsequent applications for interim extension are proposed to be moved to newly proposed paragraphs (c)(1) and (d)(1), respectively, of this section.

Section 1.790(b) is proposed to be amended to require any application for interim extension under this section (i.e., both initial and subsequent interim extension applications) to be filed using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements. The provisions in the current § 1.790(b) regarding a complete application for interim extension are proposed to be moved to newly proposed paragraph (c)(2) of this section.

Section 1.790(c) is proposed to be amended to provide the requirements for complete initial applications for interim extension. Newly proposed § 1.790(c)(1) contains the time period in the current § 1.790(a) for filing an initial interim extension application. Newly proposed § 1.790(c)(2) contains the provisions in the current § 1.790(b) regarding a complete interim extension application. Note that the reference in the current § 1.790(b) to § 1.740(a)(16) and (17) is proposed to not be included in newly proposed § 1.790(c)(2) to correct an oversight. Paragraphs (a)(16) and (17) were removed from § 1.740 on September 8, 2000. Newly proposed § 1.790(c)(3) requires a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has begun for the product. It also requires an identification of the application, petition, or notice that caused the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii),

(2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), to begin. For a human drug, antibiotic, or human biological product, it would be the number associated with the new drug application or Product License Application submitted for the product. For a new animal drug, it would be the number associated with the new animal drug application submitted for the drug. For a veterinary biological product, it would be the number associated with the application for license submitted under the Virus-Serum-Toxin Act for the product. For a food or color additive, it would be the number associated with the petition for product approval submitted under the Federal Food, Drug, and Cosmetic Act for the additive. For a medical device, it would be the number associated with the premarket approval application or notice of completion of a product development protocol submitted for the device. The USPTO has occasionally received applications for interim extension under 35 U.S.C. 156(d)(5) and § 1.790 that fail to meet the statutory requirement regarding the applicable regulatory review period.

Newly proposed § 1.790(d) contains the requirements for subsequent interim extension applications. Newly proposed § 1.790(d)(1) contains the time period in the current § 1.790(a) for filing each subsequent interim extension application. Newly proposed § 1.790(d)(2) contains provisions in the current § 1.790(c) regarding the content of each subsequent interim extension application. Newly proposed § 1.790(d)(3) contains the requirement in the current § 1.790(c) that an application contain a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has not been completed.

Rulemaking Requirements

A. Administrative Procedure Act: The changes proposed in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (Interpretive rules "advise the public of the agency's construction of the statutes and rules which it administers." (citation and internal quotation marks omitted)); *Nat'l Org. of Veterans' Advocates v. Sec'y of Veterans Affairs*, 260 F.3d

1365, 1375 (Fed. Cir. 2001) (rule that clarifies the interpretation of a statute is interpretive); *Bachow Commc'ns Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.).

Accordingly, prior notice and opportunity for public comment for the changes proposed in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez*, 135 S. Ct. at 1206 (Notice-and-comment procedures are required neither when an agency "issue[s] an initial interpretive rule" nor "when it amends or repeals that interpretive rule."); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice-and-comment rulemaking for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" (quoting 5 U.S.C. 553(b)(A))). However, the USPTO has chosen to seek public comment before implementing this rule to benefit from the public's input.

B. Regulatory Flexibility Act: Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), whenever an agency is required by 5 U.S.C. 553 (or any other law) to publish a notice of proposed rulemaking, the agency must prepare and make available for public comment an Initial Regulatory Flexibility Analysis, unless the agency certifies under 5 U.S.C. 605(b) that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603, 605. For the reasons set forth in this document, the Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

As a threshold matter, PTE under 35 U.S.C. 156 is only available for patents that claim drug products, medical devices, food or color additives, or methods of using or manufacturing such products, devices, or additives. Approximately 100 PTE applications are filed annually,

and they are typically filed by non-small entity pharmaceutical and medical device companies because of the expense required to develop and obtain marketing approval for such inventions.

The changes proposed in this rule are procedural in nature and are not expected to result in significant costs to applicants. The current rules of practice permit follow-on documents related to PTE applications to be filed electronically. The USPTO estimates that approximately 99% of follow-on documents related to PTE applications are filed electronically. Accordingly, the proposed rule change requiring follow-on documents related to PTE applications to be filed electronically should not cause a substantial change in practice or result in additional costs to applicants. As for the proposed rule change requiring PTE applications to be filed electronically, although this would be a change in practice, stakeholders have unanimously communicated support for the USPTO's current waiver of the prohibition against electronic filing of PTE applications as a result of the COVID-19 outbreak, and the proposed rule change would not result in any additional cost to applicants. Thus, this proposed rule change requiring PTE applications to be filed electronically is not expected to negatively impact stakeholders' PTE practice.

Finally, the USPTO patent electronic filing system will allow PTE applicants to file PTE documents through their standard web browser without downloading special software, changing their documentation preparation tools, or altering their workflow processes. PTE applicants may create their documents using the tools and processes that they already use and then convert those documents into standard PDF files for submission through the USPTO patent electronic filing system.

For these reasons, the proposed changes will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This proposed rule has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The USPTO has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the USPTO has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the proposed rule; (2) tailored the proposed rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism): This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This proposed rule will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This proposed rule is not a significant energy action under Executive Order 13211 because the proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This proposed rule meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This proposed rule does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This proposed rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801-808), prior to issuing any final rule, the USPTO will submit a report containing any final rule resulting from this proposed rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this proposed rule are not expected to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this proposed rule is not a "major rule" as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The proposed changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of $100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of $100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 et seq.

M. National Environmental Policy Act of 1969: This proposed rule will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 et seq.

N. National Technology Transfer and Advancement Act of 1995: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this proposed rule does not contain provisions that involve the use of technical standards.

O. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995, the paperwork and other information collection burdens involved with this proposed rule have already been approved under the Office of Management and Budget (OMB) Control Number 0651-0020 (Patent Term Extension). However, 0651-0020 will be updated to reflect a reduction in burden (time) due to the removal of the requirement to file PTE applications in paper in triplicate. The USPTO estimates that this information collection's annual burden will decrease by a total of approximately 51 burden hours. This estimate is based on the current OMB-approved burdens (response volumes) associated with this information collection, which may fluctuate over time and may be different from any forecasts mentioned in other parts of this proposed rule.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information has a currently valid OMB control number.

P. E-Government Act Compliance: The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, the USPTO proposes to amend 37 CFR part 1 as follows:

PART 1 - RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

2. Amend § 1.740 by revising paragraphs (a)(15) and (b) to read as follows:

§ 1.740 Formal requirements for application for extension of patent term; correction of informalities.

(a) * * *

(15) The name, address, telephone number, and email address of the person to whom inquiries and correspondence related to the application for patent term extension are to be directed.

(b) The application under this section, and any related submissions to the Office, must be submitted using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements.

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3. Amend § 1.741 by revising paragraph (a) introductory text to read as follows:

§ 1.741 Complete application given a filing date; petition procedure.

(a) The filing date of an application for extension of a patent term is the date on which a complete application is either received in the Office via the USPTO patent electronic filing system or filed pursuant to the procedure set forth in § 1.8(a)(1)(i)(C) and (a)(1)(ii). A complete application must include:

* * * * *

4. Amend § 1.770 by revising the first sentence to read as follows:

§ 1.770 Express withdrawal of application for extension of patent term.

An application for extension of patent term may be expressly withdrawn before a determination is made pursuant to § 1.750 by filing in the Office a written declaration of withdrawal signed by the owner of record of the patent or its agent. * * *

5. Revise § 1.790 to read as follows:

§ 1.790 Interim extension of patent term under 35 U.S.C. 156(d)(5).

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) Any application for interim extension under this section must be filed using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements.

(c) Complete initial applications for interim extension under this section must:

(1) Be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire, and include a statement that the initial application is being submitted within the period and an identification of the date of the last day on which the initial application could be submitted;

(2) Include all of the information required for a formal application under § 1.740 and a complete application under § 1.741, except as follows:

(i) Paragraphs (a)(1), (2), (4), and (6) through (15) of §§ 1.740 and 1.741 shall be read in the context of a product currently undergoing regulatory review; and

(ii) Paragraphs (a)(3) and (5) of § 1.740 are not applicable to an application for interim extension under this section; and

(3) Include a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has begun for the product that is the subject of the patent, and identify the application, petition, or notice that caused the applicable regulatory review period to begin.

(d) Each subsequent application for interim extension:

(1) Must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension and include a statement that it is being submitted within the period and an identification of the date of the last day on which it could be submitted;

(2) May be limited in content to a request for a subsequent interim extension along with any materials or information required under §§ 1.740 and 1.741 that are not present in the preceding interim extension application; and

(3) Must include a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has not been completed.

Katherine K. Vidal,
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.
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